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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/763,466 | 01/22/2004 | Alan M. Nelson | 273102008401 | 6665 |
| 25225 7590 03/25/2008 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040 | | | EXAMINER LAM, ANN Y | |
| | | | ART UNIT 1641 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/763,466 | Applicant(s) NELSON ET AL. | |
| | Examiner ANN Y. LAM | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10 is/are pending in the application.
- 4a) Of the above claim(s) 11-16, 21-24 and 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenquist, 4,806,312, in view of Georgevich, 5,200,317.

Greenquist teaches a multilayer device having a first reagent layer incorporated with a labeled reagent comprising an antibody with binding affinity for the analyte, which has been previously labeled with an enzyme, and a detection layer incorporated with an immobilized form of a substrate for the enzyme wherein the analyte (labeled-reagent) complex interacts with the immobilized substrate to thereby generate a reaction product. The reaction product can be generated as a detectable species, or it may be generated in a form which requires further interaction with an additional substance, such as an indicator, to provide a detectable signal. In the latter case, it is then preferable to incorporate an immobilized form of such indicator in order to localize the signal produced thereby in the detection layer (col. 13, lines 12-39.)

Greenquist also disclose that the device has an absorbtive pad that serves as a wick for the absorption of the test medium and the upward diffusion thereof into the first reagent, zone, a second reagent zone, and the detection zone, respectively. The

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analyte from the test medium diffuses into the first reagent zone binds to the labeled reagent incorporated therein and the complex formed thereby migrate through the second reagent zone and into the detection zone where the analyte (labeled reagent) complex interacts with the interactive detection reagent immobilized therein to thereby generate the reaction product for the further detection and measurement. (col. 14, lines 52 - col. 15, line 44.)

The Greenquist absorbtive pad is equivalent to Applicant's sample pad, the Greenquist first reagent zone is analogous to Applicant's label pad, and the Greenquist detection zone is analogous to Applicant's capture zone having an enzyme substrate at a test line (the test line being where the enzyme substrate is located).

However, Greenquist does not disclose an embodiment wherein the analyte binds to an antibody binding partner that is labeled with an enzyme (rather than previously labeling the analyte with an enzyme) and the detection zone having 1) a secondary antibody that binds to the analyte-antibody-enzyme complex, and 2) an enzyme substrate (rather than having just the enzyme substrate) (i.e., a sandwich assay.)

Georgevich however teaches these modifications. More specifically, Georgevich teaches a device having various zones, including a capture zone (34) that contains immobilized therein a reagent that captures conjugate directly or indirectly, so that the amount of conjugate enzyme activity passing through to the substrate zone 18 is related directly (direct conjugate capture) or inversely (indirect conjugate capture) to the amount of analyte present. In one variation of the indirect method, all analyte passing through

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the conjugate zone 32 becomes labeled by complexing with the excess conjugate.

Thereafter, enzyme labeled analyte passes to the capture zone 34 and becomes immobilized on the stationary phase by forming an antibody:analyte:conjugate sandwich with the immobilized second antibody (col. 7, lines 19-37.) Because this immobilized analyte bears an enzyme label from the conjugate zone, the amount of enzyme passing to the substrate zone 18 is inversely related to the amount of analyte present in the sample. (col. 8, lines 10-40). Georgevich teaches that this method is particularly well suited for analyzing larger molecular weight antigens and macromolecules which have more than one antigenic site per molecule (col. 8, lines 41-46.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Greenquist invention such that a sandwich assay as taught by Georgevich because Georgevich teach that this method is an alternative method for detection of analyte and is particularly well suited for analyzing larger molecular weight antigens and macromolecules which have more than one antigenic site per molecule.

As to claim 6, Greenquist teaches that it is preferable to incorporate an immobilized form of the indicator (e.g., substrate) in order to localize the signal produced thereby in the detection layer. (col. 34) It is understood from the disclosure of Greenquist that the immobilization is chemical (see also col. 15, lines 59-67, disclosing covalent attachment.)

As to claim 7, because Applicant has not specified what constitutes the mordant, the pad containing the immobilized substrate is considered the mordant (and the area

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on the device in which the substrate is immobilized is the capture zone.) The layers are also disclosed as comprising a porous matrix (col. 15, lines 31-36). The test line is considered to be above the pad having immobilized substrate, and thus here the substrate is considered to be immobilized under the test line.

As to claim 8, the test line is considered to be wherein the pad containing substrate is located, and thus here the substrate is considered to be immobilized in a mordant within the test line (see also col. 15, lines 31-36, disclosing that the layers are also disclosed as comprising a porous matrix.)

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenquist, 4,806,312, in view of Georgevich, 5,200,317, as applied to claim 5 above, and further in view of Clark, 5,241,012.

Greenquist in view of Georgevich disclose the invention substantially as claimed (see discussion of claim 5 above). However, while Greenquist teaches that the substance, such as an indicator, to provide a detectable signal, is preferable to incorporate an immobilized form of such indicator in order to localize the signal produced thereby in the detection layer (col. 13, lines 12-39), Greenquist does not teach that the capture zone further comprises chemical groups incorporated therein, capable

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of specifically reacting with the product, resulting from enzyme action on the substrate (claim 9), wherein said chemical groups comprises diazotized amines (claim 10).

Clark however teaches this. More specifically, Clark teaches that various reactions may be carried out to link compounds of interest to the solid substrate surface (col. 4, lines 11-61), and the compounds which are linked include ligands such as haptens and antigens, receptors such as antibodies, enzymes, enzyme substrates, etc. (col. 6, lines 32-45). Clark specifically gives the example of the reaction of nitroso groups with amines. Aryl amines are known to undergo a wide variety of reactions and may be acylated under a variety of conditions (col. 4, lines 11-61). Clark also specifically discloses that the amino group may be reacted with a nitroso compound to form an azo linkage (col. 4, lines 11-61), and that amines may be diazotized, where the amines may be substituted with a wide variety of functional groups, such as halides, acyl groups, etc.

It would have been obvious to one of ordinary skills in the art to utilize diazotized amines in the capture zone of the Greenquist device because Clark teaches that this provides for linking a compound or complex to a solid substrate, and the skilled artisan would recognize that this serves the purpose suggested by Greenquist of incorporating an immobilized form of an indicator to localize the signal produced in the detection area, as would be desirable for more accurate results.

Response to Arguments

The 112, second paragraph rejections made in the previous Office action has been withdrawn for the reasons as stated in the interview of December 28, 2007. However, Applicant's claims are unpatentable over the prior art as discussed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Ann Y. Lam/
Primary Examiner, Art Unit 1641